NIH POLICY MANUAL

54442 - SBIR/STTR Fast Track Award Policy
Issuing Office: OPERA/OER/OD 301-435-0949
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1. **Explanation of Material Transmitted:** This chapter provides updated policies and procedures for administering National Institutes of Health grant awards submitted under the SBIR/STTR Fast-Track application procedures.
2. **Filing Instructions:**

   Remove: NIH Manual Chapter 4442 dated 03/15/2001

   Insert: NIH Manual Chapter 4442 dated 08/01/2003

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SBIR/STTR Fast Track Award Policy

A. Purpose: This chapter outlines the responsibilities and operating procedures for awarding Small Business Innovative Research/Small Business Technology Transfer Research Fast Track grants.

B. Background: The SBIR/STTR Programs are structured in three phases, the first two of which are supported using SBIR/STTR funds. Traditionally, SBIR and STTR applicants submit two distinct applications for each of the two phases. Phase I establishes the technical merit and feasibility of proposed research. Phase II continues the research efforts initiated in Phase I with the ultimate goal of achieving commercialization of the results. No Federal SBIR or STTR funds may be used to support Phase III, the commercialization phase. Small firms are encouraged to pursue this phase through private sector commercialization or by obtaining non-SBIR/STTR government follow-on contracts for additional technology development. Previously, the Phase II application could not be submitted until after the Phase I application had been funded. The Fast-Track mechanism expedites the decision and award of SBIR and STTR Phase II funding for scientifically meritorious applications that have a high potential for commercialization. Fast-Track incorporates a submission and review process in which both Phase I and Phase II grant applications are submitted and reviewed together.

Fast-Track SBIR/STTR applications are eligible for consideration upon meeting the following criteria:

1. Fast-Track SBIR/STTR applications for both Phase I and Phase II must be submitted together for concurrent initial peer review and evaluation. The PHS 398 application forms are available at http://grants1.nih.gov/grants/funding/phs398/phs398.html.
2. In order to identify the application as such, the words "Fast-Track" must be shown on line 2 of the face page of the Phase I and Phase II applications.
3. The Phase I application must specify clear, measurable goals (milestones) that should be achieved prior to initiating Phase II. Failure to provide clear, measurable goals may be sufficient reason for the scientific peer review group to exclude the Phase II application from Fast-Track review. The scientific peer review group will evaluate the goals and may suggest other milestones that should be achieved prior to Phase II funding. The Phase I and Phase II applications will receive a concurrent review. Fast-Track applications will receive secondary review by the advisory council or board of the NIH awarding component that is the potential funding component. Staff will review progress after Phase I prior to any decision to award Phase II funds.

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4. The small business concern must submit as a part of the Phase II research plan, a concise Commercialization Plan [formerly Product Development Plan] (limited to fifteen pages). It should address each of the following areas:

Value of the SBIR/STTR Project, Expected Outcomes, and Impact. Describe, in layperson's terms, the proposed project and its key technology objectives. Clarify the need addressed, specifying weaknesses in the current approaches to meet this need. In addition, describe the commercial applications of the research and the innovation inherent in this application. Be sure to also specify the potential societal, educational, and scientific benefits of this work. Explain the non-commercial impacts to the overall significance of the project. Explain how the SBIR/STTR project integrates with the overall business plan of the company.

Company. Give a brief description of your company including corporate objectives, core competencies, present size (annual sales level and number and types of employees), history of previous Federal and non-Federal funding, regulatory experience, and subsequent commercialization, and any current products/services that have significant sales. Include a short description of the origins of the company. Indicate your vision for the future, how you will grow/maintain a sustainable business entity, and how you will meet critical management functions as your company evolves from a small technology R&D business to a successful commercial entity.

Market, Customer, and Competition. Describe the market and/or market segments you are targeting and provide a brief profile of the potential customer. Tell what significant advantages your innovation will bring to the market, e.g., better performance, lower cost, faster, more efficient or effective, new capability. Explain the hurdles you will have to overcome in order to gain market/customer acceptance of your innovation. Describe any strategic alliances, partnerships, or licensing agreements you have in place to get FDA approval (if required) and to market and sell your product. Briefly describe your marketing and sales strategy. Give an overview of the current competitive landscape and any potential competitors over the next several years. (It is very important that you understand and know the competition.)

Intellectual Property (IP) Protection. Describe how you are going to protect the IP that results from your innovation. Also note other actions you may consider taking that will constitute at least a temporal barrier to others aiming to provide a solution similar to yours.

Finance Plan. Describe the necessary financing you will require, and when it will be required, as well as your plans to raise the requisite financing to launch your

innovation into Phase III and begin the revenue stream. Plans for this financing stage may be demonstrated in one or more of the following ways:

- Letter of commitment of funding.
- Letter of intent or evidence of negotiations to provide funding, should the Phase II project be successful and the market need still exist.
- Letter of support for the project and/or some in-kind commitment, e.g., to test or evaluate the innovation.
- Specific steps you are going to take to secure Phase III funding.

Production and Marketing Plan. Describe how the production of your product/service will occur (e.g., in-house manufacturing, contract manufacturing). Describe the steps you will take to market and sell your product/service. For example, explain plans for licensing, internet sales, etc.

Revenue Stream. Explain how you plan to generate a revenue stream for your company should this project be a success. Examples of revenue stream generation include, but are not limited to, manufacture and direct sales, sales through value added resellers or other distributors, joint venture, licensing, service. Describe how your staffing will change to meet your revenue expectations.

Applicants are *encouraged to seek commitment(s) of funds and/or resources from an investor or partner organization for commercialization* of the product(s) or service(s) resulting from the SBIR/STTR grant. *Place relevant letters following letters from consultants and collaborators*.

Phase III funding may be from any of a number of different sources including, but not limited to: SBIR/STTR firm itself; private investors or "angels"; venture capital firms; investment companies; joint ventures; R&D limited partnerships; strategic alliances; research contracts; sales of prototypes (built as part of this project); public offering; state finance programs; non SBIR-funded R&D or production commitments from a Federal agency with the intention that the results will be used by the United States government; or other industrial firms.

C. Policy: Fast-Track Phase II applications may be funded following submission of the Phase I progress report and other documents necessary for continuation. Phase II applications will be selected for funding based on the awarding component's assessment of the Phase I progress report, and determination that the Phase I goals were achieved; an update and verification of the Commercialization Plan [formerly Product Development Plan] and any commitment(s) for funds and/or resources from an investor or partner organization, as described below; the project's potential for meeting the mission of the awarding component and for commercial success; and the availability of funds.

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D. References

1. Small Business Innovation Research Program Reauthorization Act of 2000, Public Law 106-554 http://www.acq.osd.mil/sadbu/sbir/pl106-554.pdf

2. Small Business Technology Transfer Program Reauthorization Act of 2001, Public Law 107-50 http://www.acq.osd.mil/sadbu/sbir/pl107-50.pdf.

3. Omnibus Solicitation of the NIH, CDC and FDA for SBIR/STTR Grant Applications at: http://grants.nih.gov/grants/funding/sbir.htm

4. Small Business Innovation Research (SBIR) Program Policy Directive at http://www.sbaonline.sba.gov/SBIR/sbirpolicydirective.html

E. Definition:

1. Fast-Track. A review option available to those small business concerns (applicant organizations) whose applications simultaneously satisfy review criteria for both Phase I and Phase II, which enhances the probability of the project's commercial success. Applications that do not meet these criteria may be redirected for review through the standard peer review procedures. In some cases, the Scientific Review Group may review and score only the Phase I portion of a Fast Track application, if the application does not include a Commercialization Plan that includes the seven items listed in Section B.4 above, or the application does not contain clear, measurable Phase I goals that are appropriate for demonstrating feasibility, or the Phase II project is significantly less meritorious than the Phase I project. Fast Track offers two major advantages:

   a) Concurrent submission and peer review of both Phase I and Phase II projects.

   b) Minimal or no funding gap between Phase I and Phase II.

F. Responsibilities: In addition to the standard Program and Grants Management responsibilities, the following reflect specific responsibilities applicable to this mechanism:

The Program Director is responsible for

- negotiating the Phase I milestones with the PI;
- determining whether the milestones have been achieved prior to the Phase II award; and
- communicating with the PI regarding this complex mechanism.

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The Grants Management Specialist is responsible for coordinating the activities necessary to ensure a smooth transition to the Phase II award. This includes:

- establishing the administrative deadlines to ensure a minimal funding gap;
- notifying the appropriate IC staff regarding the potential start date of Phase II and anticipated total costs for each year; and
- communicating with the grantee regarding this complex mechanism

G. Procedures: Under the Fast-Track initiative, two distinct applications (Phase I & Phase II) are simultaneously submitted and reviewed.

1. Phase I:

a) The Phase I is entered into IMPAC II as a Type 1 R44 (SBIR)/R42 (STTR) at the time of receipt by the Center for Scientific Review (CSR).

b) The Phase I will be funded as a Type 1 R44/R42, with no commitment for Phase II in future years.

c) For Phase I administrative review, the appropriate IC Phase I checklist should be used.

d) For Fast-Track Phase I awards, automatic carryover authority from Phase I to Phase II and the Streamlined Non-competing Award Process (SNAP) apply.

e) An FSR and invention report for the final Phase I budget period will be required 90 days after Phase I ends, so the common FINAL YEAR footnote should be included on all awards to ensure notification of this requirement.

f) In addition to the standard SBIR/STTR footnotes, the Phase I Notice of Grant Award (NGA) should include the following terms and conditions of award:

> "The Fast-Track Phase II application may be funded following submission of an original PHS 2590 Non-competing Grant Progress Report (plus two copies). Follow the simplified instructions under the Streamlined Noncompeting Award Process (SNAP) found at: http://grants1.nih.gov/grants/funding/2590/phs2590.pdf.
> for all portions except the research plan, which should include the following:
>
> • A Phase I Final Progress Report: Follow the application instructions in the NIH SBIR/STTR Phase II Solicitation: Section 8. Research Plan, Item c. Preliminary Studies/Phase I Final Report at

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http://grants1.nih.gov/grants/funding/sbirsttr2/PhaseII_SBIRSTTR.pdf or
http://grants.nih.gov/grants/funding/sbirsttr2/PhaseII_SBIRSTTR.doc

- A section labeled Milestones (l) identifying either the milestones described in the original Phase I application as approved by the peer reviewers or the milestones modified by the peer reviewers and negotiated with the grantee; and (2) describing the progress achieved relative to the milestones.

- A one-page abstract describing the research plan for Phase II . (See Section 6. D, "Plans" of the progress report summary). If the aims have not been modified from the original Phase II application, state this. If they have been modified, give the reviewed aims and the reason for the modifications.

- An updated Commercialization Plan [formerly Product Development Plan] as necessary, if changes have been made from the original submission.

Funding for the Phase II application will be contingent upon (1) assessment of the Phase I progress report and determination that the Phase I goals and milestones were achieved; (2) An update (as necessary) of the Commercialization Plan; (3) determination of the project's potential for meeting the mission of the awarding component and for commercial success; (4) review and approval of other documents necessary for continuation; and (5) availability of funds.

The Grant Progress Report is due two months prior to the anticipated start of Phase II and should be sent to the following address:

(fill in blank)

The appropriate grants management and program staff of the awarding component will review the Phase I Grant Progress Report. If the continuation request is not approved, written notification will be sent to the applicant."

[NOTE: It is possible for the IC to delay a funding decision for the Phase II application due to the need for a specified amount of time to fulfill/accomplish the established milestones. It is also possible for the IC to expedite funding for the Phase II if the milestones are completed before the originally anticipated start date.]

g) When the Phase I NGA is issued, grants management staff should notify the appropriate IC staff regarding the potential start date of the Phase II and anticipated total costs for each year.

h) The grants management specialist will create the Phase II Type 4 record in IMPAC after the Phase I award is released. Budget information may be included at this time for the Phase II.

Beginning with FY2003 Phase 1 competing grants, sample sequence of events in IMPAC and for the PMS for multiple years PhaseI/Phase II Fast-Track are:

Grant Number		Document Number
1 R44 AZ12345-01	Phase I first year	RAZ123456A
5 R44 AZ12345-02	Phase I second year	RAZ123456A
4 R44 AZ12345-03	Phase II first year	RAZ123456B
5 R44 AZ12345-04	Phase II second year	RAZ123456B

i) At the option of the IC, the Program Director should send a letter to the grantee (countersigned by the GMO) establishing and defining the process for receipt of the Phase II award. This letter should include evaluation criteria for acceptable progress, clear definition of the milestones, review issues expressed in the Summary Statement, and any other relevant expectations.

The informational letter included as Appendix 2 should be sent to the grantee organization after the Phase I award has been issued. This will provide for receipt of the above information and help ensure a smooth transition to Phase II.

j) The grants management specialist must notify the grantee of the F&A (IDC) rate negotiation requirement. For grantees that do not currently have a negotiated F&A (IDC) rate agreement with the Federal government, the IDC rate for Phase I is the proposed rate not to exceed 40% of total direct costs (no base exclusions). The Division of Financial Advisory Services (DFAS), NIH will not negotiate an IDC rate agreement for Phase I awards.

If the requested IDC rate for Phase II exceeds 25% of the total direct costs (no base exclusions), the grants management specialist must notify the grantee of the IDC rate negotiation requirement. The grantee should contact DFAS at (301) 496-2444 at the time the Phase I is awarded.

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a) The Phase II will be awarded as a Type 4 R44/R42. The Phase II award should normally be included under SNAP and given carryover authority.

b) The Grant Progress Report is due to the awarding I/C two months prior to the end of the Phase I award.

c) It is recommended that a letter be sent at least four months in advance of the Phase II start to inform the grantee organization of the process for insuring a smooth transition to Phase II. A generic version of this letter is included as Appendix 2 at the end of this document.

d) When the Grant Progress Report (PHS 2590) is received, the Grants Management Specialist will forward the information to the Program Director (PD) for review of progress and achievement of the stated milestones. It may be appropriate for an outside reviewer to be involved in this process. If the PD determines that progress has not been adequate, additional information may be requested. If the PD ultimately determines that adequate progress has not been made, the grantee must be advised of the decision in a letter written by the PD, countersigned by the GMO, along with advice of the option of submitting a competing Phase II application for the non-Fast-Track peer review.

e) After the review is complete, the PD will indicate his/her recommendation for Phase II funding by completing the appropriate IC documentation. Since both Phase I and Phase II applications received simultaneous review by Council, there should be no need for additional Council discussion before deciding to fund the Phase II.

f) A streamlined review of the Phase II should be documented by using the appropriate IC checklist. Verify that the IDC rate is the current negotiated rate. If the proposed rate does not exceed 25% of total costs (no base exclusions), the grantee is not required to have a negotiated rate.

Once these issues have been addressed satisfactorily, the award can be processed.

H. Records Retention and Disposal: All records (e-mail and non-e-mail) pertaining to this chapter must be retained and disposed of under the authority of NIH Manual 1743,"Keeping and Destroying Records," Appendix 1, 'NIH Records Control Schedule, 'Section 4000 covers NIH Grants and Awards and Section 1100-G covers Advisory Councils and Committee Management. Refer to the NIH Chapter for specific instructions.

NIH E-mail messages. NIH e-mail messages (messages, including attachments, that are created on NIH computer systems or transmitted over NIH networks) that are evidence of

the activities of the agency or have informational value are considered Federal records. These records must be maintained in accordance with current NIH Records Management guidelines. If necessary, back-up file capability should be created for this purpose. Contact your IC Records Officer for additional information.

All e-mail messages are considered Government property, and, if requested for a legitimate Government purpose, must be provided to the requestor. Employees' supervisors, NIH staff conducting official reviews or investigations, and the Office of Inspector General may request access to or copies of the e-mail messages. E-mail messages must also be provided to members of Congress or Congressional oversight committees if requested and are subject to Freedom of Information Act requests. Since most e-mail systems have back-up files that are retained for significant periods of time, e-mail messages and attachments are likely to be retrievable from a back-up file after they have been deleted from an individual's computer. The back-up files are subject to the same requests as the original messages.

I. Management Controls: The purpose of this manual issuance is to state NIH policies and the requirements governing the acceptance and administration of SBIR/STTR Fast-Track Awards.

1. **Office Responsible for Reviewing Management Controls Relative to this Chapter:** The Office of Policy for Extramural Research Administration (OPERA), Office of Extramural Research (OER).

2. **Frequency of Review:** The frequency of review will be based on the outcome of a risk assessment that will determine how often a management control review will be conducted to assess IC compliance with this issuance. Manual issuances with high-risk ratings will receive a more frequent and/or detailed review and will receive the highest priority in the review schedule.

3. **Method of Review:** OPERA will utilize the NIH Management Controls Compliance Model (MCCM) as described in the GMAC Policy and Procedure Announcement 2000-01. This model will assess IC compliance with the policies stated in this issuance and determine if policies are correct, clear, and effectively written. The Management Controls Compliance Model Board will be responsible for the development of a customized compliance checklist. This checklist will be used when reviewing files or electronic data to determine compliance with this issuance. A fundamental concept of the MCCM is to use a sampling method instead of an Institute-by-Institute review in order to determine NIH-wide compliance.

4. **Review Reports are sent to**: The review findings will be presented in the form of a draft report that will be provided to Chief Grants Management Officers(s) for comment with a copy to the Director, OPERA. A final report will be provided to Chief Grants Management Officers, IC Extramural Activities Directors or Executive Officers, as appropriate, the Deputy Director of Extramural Research, the Director, OPERA, and the Deputy Director for Management.

APPENDIX 1

FREQUENTLY ASKED QUESTIONS

Q: Can both Phases be funded from the same fiscal year?

A: Yes. Since each Phase is considered a distinct competitive segment (even though reviewed together) multi-year funding is not an issue.

Q: If program staff determines that progress has not been adequate and the Fast-Track Phase II is not recommended for funding, is that decision appealable?

A: No. The decision to fund or not to fund the Fast-Track Phase II is considered a preaward action. As such, it is not appealable. The grantee has the option of submitting a non-Fast-Track Phase II application for peer review. There are established time frames for submitting a Phase II application.

APPENDIX 2

INFORMATIONAL LETTER
TO PHASE I AWARDEES OF SBIR/STTR FAST-TRACK APPLICATIONS

To be sent out after the Phase I award has been issued and four months in advance of Phase II.

Our Reference:

Dear:

As a recipient of a Fast-Track SBIR/STTR grant, we would like to insure that the transition from Phase I to Phase II is completed as smoothly and expeditiously as possible. The Fast-Track mechanism provides an opportunity for your research to proceed from Phase I to Phase II without the normal hiatus that occurs when only the Phase I application is funded and Phase II depends on a formal application and review. However, in order for the Phase II (Type 4) application to be funded, progress under

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Phase I must be evaluated and deemed successful, based on the expectations stated in the initial application.

The purpose of this letter is to inform you of the process that has been instituted to ensure that all Fast-Track Phase II applications receive an appropriate scientific evaluation.

Two months before the end of the Phase I budget period, or as soon as you have sufficient data to demonstrate that the stated milestones have been accomplished, you must complete a PHS 2590 application. This is the standard non-competing grant progress report continuation application, which is available at the following URL: http://grants.nih.gov/grants/funding/2590/2590.htm. In order for the Program Director to evaluate whether or not you have achieved your Phase I milestones, your PHS 2590 Progress Report summary should include:

- A Phase I Final Report: Follow the application instructions in the NIH SBIR/STTR Phase II Instructions. See Section 8. Research Plan, Item c. Preliminary Studies/Phase I Final Report at http://grants1.nih.gov/grants/funding/sbirsttr2/PhaseII_SBIRSTTR.pdf or http://grants.nih.gov/grants/funding/sbirsttr2/PhaseII_SBIRSTTR.doc
- **A section labeled Milestones**: (l) Identify either the milestones described in the original Phase I application as approved by the peer reviewers or the milestones modified by the peer reviewers and negotiated with the grantee; and (2) Describe the progress achieved relative to the milestones.
- **A one-page Abstract**: Describe the research plan for Phase II . (See Section 6. D, "Plans" of the Progress Report summary). If the aims have not been modified from the original Phase II application, state this. If they have been modified, give the reviewed aims and the reason for the modifications.
- **An updated Commercialization Plan** [***formerly Product Development Plan***], as necessary, if changes have been made from the original submission.
- Any specific concerns conveyed in the summary statement from the initial review of the Phase I application; and
- Any additional documentation that the Program Director requests in order to evaluate progress.

The application should be sent to the following address:

(fill in blank)

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If you have not accomplished the milestones set out in Phase I, you may wish to delay your request to start Phase II. In such a case, you should notify the Grants Management Specialist named on the Notice of Grant Award of your intent to extend the Phase I without additional funds after you have discussed this situation with the Program Director.

Once we receive the Phase II application (PHS 2590), the Program Director will evaluate the application with respect to success in meeting the Phase I milestones. Outside opinions may be obtained as part of this process. If progress is deemed adequate, the Phase II award will be made after Grants Management has reviewed the fiscal and administrative aspects of the application. If the evaluation is unfavorable, there are two options:

(1) You may extend the Phase I project for up to 12 months additional time in order to meet the milestones. You must notify the Grants Management Specialist named on your Notice of Grant Award of the extension; however, you should not request additional funds to enable you to meet the Phase I milestones.

(2) It may be necessary to remove the application from the Fast Track process and submit a competing Phase II application through the regular SBIR/STTR process.

If you have any questions regarding this process, please contact the Program Director for scientific and technical guidance and the Grants Management Specialist (Officer) for administrative and fiscal advice. Also, it would be very beneficial if you would contact the Program Director for advice prior to preparing the Phase II application.

Sincerely,

Program Director
(Officer)

Grants Management Specialist

bcc:
Grants Management
Program File

Last Updated: 02/21/2003